UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,731	08/10/2001	Monisola Adeokun	P 0282795 100135 US	4818

7590 10/29/2002

Janis K. Fraser, Ph.D.,J.D.
Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110

EXAMINER
EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1634	14

DATE MAILED: 10/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/925,731	Applicant(s) ADEOKUN ET AL.
	Examiner Juliet C Einsmann	Art Unit 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 2, drawn to methods for the detection of polymorphisms and use of such a method to assess the pharmacogenetics of a drug, classified in class 435, subclass 6.

II. Claims 3-6, drawn to polynucleotides comprising allelic variants, classified in class 536, subclass 23.4.

III. Claims 1 and 7, drawn to methods for the detection of polymorphisms and the use of such a methods in linkage studies, classified in class 435, subclass 6

IV. Claims 1 and 8-10, drawn to methods for the detection of polymorphisms and methods for treating patients, classified in class 435, subclass 6 and class 424, for example.

V. Claim 11, drawn to allelic variant polypeptides, classified in class 530, subclass 350.

VI. Claim 12, drawn to an antibody, classified in class 530, subclass 395.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II, inventions II and III, and inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of

invention II can be used in a variety of methods as is exemplified by the instantly claimed methods. In addition, the polynucleotides of invention II can be used in aptamer methods and nucleic acid purification methods.

3. Inventions I and III, inventions I and IV, and inventions III and IV are drawn to methods that have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). It is noted that the methods of inventions I, III, all share claim 1 in common. To the extent that each of these claims utilizes the method of claim 1, these claims are related, but the claim are also patentably distinct since they are drawn to methods that have different goals, require different method steps and would utilize separate reagents. The methods of invention I are drawn to the assessment of the pharmacogenetics of a drug and would require dosing studies on large populations to monitor patient response. The methods of invention II are drawn to linkage analysis and would require the study of patient populations in order to determine a relationship between a particular phenotype and a polymorphism or between a locus and a polymorphism. The methods of invention IV have the goal of treating humans and require a step of administering a drug to a human in need of treatment. have some claims in common. Claim 1 will be examined with either group I or group III or group IV, if one of these is elected. It is also noted that claims 2 and 7 are currently drawn to non-statutory "use" claims which do not actually recite method steps. These claims have been grouped for restriction purposes as method claims based on the recitations of the claims and the disclosure. It is recommended that applicant amend these claims prior to examination, as appropriate, if elected.

4. The methods of groups I, III, and IV are unrelated to the products of groups V and VI. The methods of groups I, II, and IV do not recite or require the products of groups V and VI.

5. The inventions of Groups II, V, and VI are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acids of Group II is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The polypeptide of Group V is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibody of Group VI is also composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. Furthermore, the products of Groups II, V, and VI can be used in materially different processes, for example, the DNA of Group II can be used in hybridization assays, the antibody of Group VI can be used in immunoassay, the polypeptide of Group V can be used to make fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups II, V, and VI are patentably distinct from each other.

Further Restriction Requirement Applicable to All Groups

Each group detailed above reads on more than one patentably distinct group, wherein each of the distinct group claims or utilizes one of the distinct polymorphisms that are recited within the claims. For example, group I above encompasses eight different inventions, that is, methods for detecting each of the twenty eight different nucleic acid polymorphisms. **For the elected group (of groups I-VI), applicants must further elect <u>single</u> polymorphism for**

examination in the appropriate product or method claim. Applicant should identify the polymorphism being elected as well as any particular SEQ ID NO's related to the polymorphism, as appropriate. For example, if applicant elects group I, applicant should further elect one of the polymorphisms for examination.

Prior to allowance, non-elected subject matter will be required to be deleted from any allowable claims. Applicant is advised that examination will be restricted to only the elected SNP and SEQ ID NO. and this restriction should not to be construed as a species election.

Each polymorphic sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity. Further, even where the nucleic acid changes have no effect on protein structure or function, these sequences themselves represent allelic variations which have different diagnostic and therapeutic implications. A reference against one would not anticipate or obviate another, and thus for each particular sequence a separate search of the patent and non-patent literature is required. These separate searches would impose undue burden on the examiner.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-VI, and each individual polymorphism require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600

Juliet C. Einsmann
Examiner
Art Unit 1634

October 21, 2002